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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/282,622	01/12/99	GATELY	M 1048

EXAMINER	
CUSTER, T	
ART UNIT	**PAPER NUMBER**
1644	3

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DATE MAILED: 06/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary	Application No. 09/232,522	Applicant(s) Gately et al.
	Examiner Tara Custer	Group Art Unit 1644

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-36* is/are pending in the application.

Of the above, claim(s) *34-36* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-33* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, drawn to a human IL-12 antibody, classified in class 424, subclass 143.1.

II. Claim 34, drawn to a method for producing an antibody that reacts with the human IL-12 p75 heterodimer, classified in class 530, subclass 387.9

III. Claims 35-36, drawn to a method for producing a monoclonal antibody that reacts with the human IL-12 p75 heterodimer, classified in class 530, subclass 388.1.

2. The inventions are distinct, each from the other because of the following reasons:
Inventions II and III are different methods. These inventions require different ingredients, process steps, and endpoints to achieve different goals. Group II is drawn to a method for producing an antibody that reacts with the human IL-12 p75 heterodimer, and Group III is drawn to a method for producing a monoclonal antibody that reacts with the human IL-12 p75 heterodimer. Therefore they are patentably distinct one from the other.

3. Inventions I and II are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the products as claimed can be made by a materially different process such as affinity purification or other detection assays.

4. Inventions I and III are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the products as claimed can be made by a materially different process such as affinity purification or other detection assays.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-III is not required for any other group from Groups I-III and Groups I-III have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. Claims 6-13, 21-28, 30, and 31-33 are generic to a plurality of disclosed patentably distinct species comprising:

A) HB-12446 (claims 6-7, 21-22, and 30)
B) HB-12447 (claims 8-9, 23-24, and 31)
C) HB-12448 (claims 10-11, 25-26, and 32)
D) HB-12449 (claims 12-13, 27-28, and 33)

These species are distinct because each salt is distinct from the others, having different physical and chemical features and different functions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. During a telephone conversation with George Johnston on 2/25/99, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-33, species B (HB-12447). Affirmation of this election must be made by applicant in replying to this Office action. Claims 34-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Claims 1-33 are under consideration.

Specification

9. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e). An application in which the benefits of an earlier application are desired must contain a specific reference to the earlier filed application(s) in the first sentence of the specification (37 CFR 1.78). A statement reading "This application claims priority to Provisional Application Serial No. 60/072,333, filed 1/23/98" should be entered following the title of the invention or as the first sentence of the specification.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 6-13, 21-28, and 30-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the monoclonal antibody produced by the hybridoma ATCC designation number HB-12446 or HB-12447 or HB-12448 or HB-12449 and said hybridomas are required to practice the instant invention. As a required element, the hybridoma producing said antibody must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If said hybridoma is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the instant cell line. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the aforementioned hybridoma. There is no disclosure in the specification as to the epitope bound by said antibody or the primary amino acid sequence of said antibody or the nature of glycosylation found in said antibody. Therefore a routineer would not be able to produce said antibody based on the disclosure of the specification. Deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. 112.

In addition, the identifying information set forth in 37 CFR 1.809 (d) should be added to the specification. See 37 CFR 1.801-1.809 for additional explanation of these requirements. The requirements under 37 CFR 1.808 can be met by submission of an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability of the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3 is indefinite in the recitation of "immunologically reacts with" because the characteristics of the phrase "immunologically reacts with" are not defined in the specification, and this term has no art recognized meaning. The language is vague and indefinite because it is unclear what "immunologically reacts with" means.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

15. Claims 1-5,29 are rejected under 35 U.S.C. 102(b) as being anticipated by Presky et al. as evidenced by Gately et al. (U.S. Patent 5,780,597). Presky et al. teach a heterodimer-specific humanized monoclonal antibody produced from a murine cell line, 20C2, that reacts with IL-12 and not p40 (p. 391) and the hybridoma which makes such an antibody. The hybridoma producing said antibody does not encode the gene for human p35 or p40. It is an inherent property of said antibody that it reacts with the p35 subunit of p75 (col. 44, line 47) and not the p40 subunit (see Gately et al.). The recitation of a method wherein the claimed antibody is made carries no patentable weight in this product claim.

16. Claims 1-4,20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cytokine Bulletin. The Cytokine Bulletin teaches a heterodimer-specific monoclonal antibody that reacts with IL-12 and not the p40 subunit of IL-12 (p. 2). It is an inherent property to produce the monoclonal antibody using a hybridoma, since all monoclonal antibodies are produced by hybridomas. The recitation of a process wherein the claimed antibody in single molecule form is produced carries no patentable weight in this product claim. The hybridoma producing said antibody does not encode the gene for human p35 or p40.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 14-17 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cytokine Bulletin.

The recitation of a process wherein the claimed antibody in single molecule form is produced carries no patentable weight in this product claim. The Cytokine Bulletin teaches a monoclonal antibody to human IL-12 that binds a heterodimer IL-12, but not the p40 subunit of the IL-12 heterodimer (p. 2). While the Cytokine Bulletin does not teach that the antibody has the properties of claims 15-17, the antibody has the specificity of such an antibody and the functional properties would be an inherent property of said antibody. Therefore the claimed antibody appears to be the same or similar to the antibody of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the antibodies of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the antibodies of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430(CCPA 1977).

19. Claims 5,18,20 are rejected under 35 U.S.C. 103(a) as obvious over Cytokine Bulletin in view of prior art disclosed in the specification (page 16).

The Cytokine Bulletin teaches a mouse anti-human IL-12 antibody (p. 1, IL-12 antibody table) that does not react with the p40 subunit of IL-12. The recitation of a method wherein said antibody is produced carries no patentable weight in this product claim. The Cytokine Bulletin does not teach a humanized version of said antibody. The specification discloses that procedures ~~fro~~ for humanizing known murine antibodies are known in the art (eg. see page 16, last paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Cytokine Bulletin teaches a mouse anti-human IL-12 antibody (p. 1, IL-12 antibody table) that

does not react with the p40 subunit of IL-12 while procedures for humanizing known murine antibodies are known in the art. One of ordinary skill in the art would have been motivated to do the aforementioned because of the art recognized advantages of humanized antibodies (eg. reduced immunogenicity when administered to humans, etc.).

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara Custer whose telephone number is (703) 305-1690. The examiner can normally be reached Monday through Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242.

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